Citation:

Gillum RF, Elmer PJ, Prineas RJ. Changing sodium intake in children. The Minneapolis Children's Blood Pressure Study. *Hypertension.* 1981 Nov-Dec; 3 (6): 698-703.

PubMed ID: 7298122

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To test the feasibility of producing lasting reduction in sodium intake of school children by a family education program.

Inclusion Criteria:

- Boys and girls enrolled in the first, second and third grades of the Minneapolis Public School System
- Children with systolic blood pressure (SBP) over the 95th percentile for age
- Completed a screening home interview.

Exclusion Criteria:

- Children with SBP>130 and/or diastolic blood pressure (DBP)>90mmHg were excluded
- Children whose weight was greater than the 95th percentile for age and sex were excluded.

Description of Study Protocol:

Recruitment

Between January through April 1978 children enrolled in the first, second and third grades of the Minneapolis Public School System were recruited to take part in a family education program to reduce dietary sodium intake.

Design

Randomized controlled trial

Dietary Intake/Dietary Assessment Methodology

- Parents were instructed in record-keeping of sodium (Na) intake at baseline, during and following the intervention for themselves and for the index child
- Completed three-day records and salt point tally sheets that were returned at each intervention meeting over the next year
- Na content of food records was assessed using United States Department of Agriculture (USDA) Handbook No. 8.
- The number of mmol of Na consumed on each of the three days was averaged, and used for analysis
- Three-day food records were collected from the control group only at the one-year follow-up.

Blinding Used

Not applicable.

Intervention

- Intervention group meetings were attended by both children and parents
- Four bi-weekly intensive 90-minute lecture demonstration sessions were followed by bi-monthly 90-minute maintenance sessions over the remainder of the year
- Parents were instructed how to obtain a 70mmol Na per day eating style for each family member
- Examples of lecture topics were: Dietary sources of Na, salt point counting (one salt point=1mmol Na)
- Examples of educational materials included low Na cookbooks and a salt point counter that indicated the Na contents of various foods
- Separately, children learned about the low-Na eating style by such means as food preparation and tasting activities.

Statistical Analysis

- The number of subjects completing assessments varied among time points
- For calculation of means and standard deviations (SD) within each group at a specified time, all available data points were used for each variable
- For calculation of changes due to intervention, subjects with valid data at both times for each variable were included
- Analysis of variance was used to compare the means and assess significance of differences among groups
- Paired T-tests were used to assess before and after changes within-group
- A two-tailed P-value of <0.05 was required for statistical significance.

Data Collection Summary:

Timing of Measurements

- The intervention group was asked to complete questionnaires, three-day food records, and 24-hour urine collections or the index child and parents at each intervention meeting over the next year
- BP was determined at the first and one-year follow-up home visit

- Three-day food records were collected from the control group only at the one-year follow-up.

Dependent Variables

- Na intake measured with:
  - Three-day food records
  - 24-hour and overnight urinary Na excretion.

Independent Variables

- Change in SBP and DBP
- Change in body height and weight
- Change in behavioral or psychological parameters due to the intervention.

Control Variables

Sex, compliance and attendance at meetings

Description of Actual Data Sample:

- *Initial N:*
  - Detailed reports about the 10,301 students surveyed have been previously published
  - 80 eligible families who gave preliminary consent were randomized with 39 in the control and 41 in the intervention groups
  - 21 families randomized to the intervention dropped out before the intervention started because they were concerned about the effort involved fully participating
- *Attrition (final N):*
  - This analysis included 36 control
  - 35 intervention subjects (including 17 attenders and 24 drop-outs)
- *Age:* Mean (SD) age at entry into study: 8.0 (0.8) and 7.8 (0.7) years for controls and intervention groups, respectively
- *Ethnicity:* Mainly white
- *Other relevant demographics:* Subjects from relatively affluent community
- *Anthropometric characteristics at entry into study:* Mean (SD); range
  - Sex
  - Control 7% female
  - Intervention 8% female
  - Attenders 12% female
  - Dropouts 10% female
  - SBP (mmHg)
    - Control 115 (8.96)
    - Intervention 111 (7.89)
    - Attenders 110 (8.96)
    - Dropouts 112 (7.04)
  - DBP (mmHg)
    - Control 69 (11.46)
    - Intervention 65 (12.62)
    - Attenders 65 (10.49)
    - Dropouts 65 (14.49)
- *Location:* Minneapolis, Minnesota.

Summary of Results:

Key Findings

Dependant variable 1 Dietary Na intake

- Reported dietary Na intake decreased by about 40% to near goal (70mmol per day) in the active intervention attenders
- Urinary Na excretion was another method to assess Na intake.

Group	Average Na Intake at One-Year Follow-Up [mmol per 24 Hours Mean (SD)]	Overnight Urinary Na Excretion Mean (SD)		
		Baseline	One Year	Change
Controls	133 (33.9)	31 (20.1)	35 (20.4)	3.7 (20.9)
Intervention	108 (37.4)	30 (15.7)	31 (13.2)	0.5 (17.3)
Attenders	87 (27.3)*	26 (10.8)	29 (16.2)	2.9 (16.5)
Dropouts	130 (35.0)**	34 (19.1)	32 (9.8)	1.9 (18.2)

Average intake overall analysis of variance for groups (control, attenders, dropout):

F=8.158; P=0.0009

*Control vs. attenders, P<0.0002

**Control vs. dropout, P=0.7729

- 24-hour urinary sodium excretion data were available for intervention families only
- While there was a significant decrease in urinary sodium excretion (24-hours) from the beginning of intervention to a six-month follow-up point, no significant (NS) differences in urinary excretion (overnight) were detected among groups at one year.

Dependant Variable 2 Change in Blood Pressure

Group	Change in SBP (SD)	Change in DBP (SD)
Controls	-2.0 (8.46)	-5.2 (18.86)
Intervention	0.5 (7.39)	-1.3 (19.8)
Attenders	1.0 (8.61)	-2.3 (18.77)
Dropouts	0.0 (6.39)	0.5 (20.97)

NS differences in SBP or DBP were detected among groups.

Independent variable 1 Change in body height and weight

NS differences were detected among groups.

Independent variable 2 Change in behavioral or psychological parameters due to the intervention

NS differences were detected among groups.

Other Findings

Compliance with diet records and urine collection was a problem in the intervention group. The number of subjects completing assessments varied among time points.

Author Conclusion:

The authors conclude that this study demonstrates the feasibility of producing long-term changes in sodium intake by family intervention in children with high-normal BP.

Reviewer Comments:

Strengths

- *The study period was for one year so there was sufficient exposure time to assess the feasibility of prolonged dietary change*
- *Data for the group as a whole, as well as attenders and dropouts, have been presented.*

Limitations

- *The authors point out that diet records may be inaccurate since it is possible that the intervention group changed their diets only at the time they were recording their three-day food record and at other times they were eating their usual sodium intake*
- *As shown by the lack of correlation between the one-year diet and urinary Na data, there was probably a reduction in compliance with the dietary restrictions or urine collection*
- *Change data for 24-hour urine and food records are not available in the control group for comparison, because those baseline data were not collected. In addition, 24-hour urinary sodium excretion data were available for intervention children only*
- *Limitations of the study, which might lead to a spurious null result, include the high drop-out rate of intervention families (21 of 41 families dropped out). Although the drop-outs occurred before the intervention started, it resulted in a significantly lower sample size, especially for the intervention group.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.		Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.		Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions			
1.		**Was the research question clearly stated?**	Yes
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
	1.3.	Were the target population and setting specified?	Yes
2.		**Was the selection of study subjects/patients free from bias?**	Yes
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
	2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.		**Were study groups comparable?**	Yes
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.		If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**		Yes
4.1.		Were follow-up methods described and the same for all groups?	Yes
4.2.		Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.		Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.		Were reasons for withdrawals similar across groups?	???
4.5.		If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**		No
5.1.		In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.		Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.		In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.		In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.		In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**		Yes
6.1.		In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.		In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.		Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.		Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.		Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.		Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?		Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?		N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?		Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?		Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?		Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?		Yes
7.5.	Was the measurement of effect at an appropriate level of precision?		Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?		Yes
7.7.	Were the measurements conducted consistently across groups?		Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?		Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?		Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?		Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?		Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?		Yes
8.6.	Was clinical significance as well as statistical significance reported?		Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?		No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
9.1.	Is there a discussion of findings?		Yes
9.2.	Are biases and study limitations identified and discussed?		Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes

| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |